exposing the library of test peptides to a sample peptide consisting of an amino acid sequence as shown in SEQ ID NO: 174;

selecting test peptides from the library that bind to the sample peptide;

screening the selected test peptides for ability to inhibit ristocetin induced aggregation of platelets; and

identifying the screened test peptides that inhibit ristocetin induced aggregation of platelets to isolate the peptide of 5 to 20 or 20 to 40 amino acid resides in length which inhibits ristocetin induced aggregation of platelets.

Pursuant to 37 C.F.R. §1.121(c)(1)(ii), a marked-up copy of the amended claims on a separate sheet accompanies this amendment

REMARKS

Applicants respectfully request that the rejections of the claims be reconsidered and withdrawn in view of the above amendments and the following remarks.

The rejection of claims 9 and 11 under 35 U.S.C. § 112(first paragraph) for lack of written description is respectfully traversed.

The specification as filed satisfies the written description requirement for the claims. In particular, page 22, lines 3-12 fully describes an isolated molecule capable of binding to an isolated peptide which comprises an amino acid sequence as shown in SEQ ID No:174. Further, the specification on page 22, lines 6-11 indicates that the isolated molecule inhibits ristocetin induced aggregation of platelets and has a three dimensional structure complementary to the three dimensional structure of the isolated peptide. Peptides of from 5 to 20 or 20-40 amino acids in length are described on page 14, lines 7-16. Further, a large number of species are listed that define the claimed genus (see

specification, page 17, line 23-page 18, line 15 and page 19, line 14-page 21, line 24). Each of the listed species of peptides is defined as meeting the limitations of the claims. Claim 11 is fully described on page 24, line 33-page 25, line 18.

Firstly, it is the position of the U.S. Patent & Trademark Office ("PTO") that the specification discloses just four closely related peptides which bind to the same single peptide (outstanding office action, paragraph 6). Applicants respectfully disagree. The specification, as described above, lists numerous species of peptides on page 17, line 23-page 18, line 15 which are capable of binding to the first peptide (page 17, lines 3-5). Further, it is the PTO's position that none of the peptides have been shown to include the recited three dimensional structure and that none of the claimed peptides have been described by structure and function. Applicants submit that the PTO is employing the improper standard in determining whether the application as filed complies the written description requirement of 35 USC § 112(first paragraph).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the invention at the time the application was filed (Guidelines for the Examination of Patent Applications Under 35 USC 112, P1, Written Description Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001)("Written Description Guidelines"). Possession may be shown in a variety of ways including a description of distinguishing identifying characteristics sufficient to show that the applicant was in possession of the invention (Written Description Guidelines at 1104). An actual reduction to practice is not required (Id.). Further, there is no requirement that the features of the invention must be defined by structure and function (Id.). As detailed above, the claimed invention was described in sufficient detail to meet

the written description requirement. Further, the limitations of claim 9 to which the PTO objects are contained in claim 9 as filed. There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed (Written Description Guidelines at 1105). Rejection of an original claim is meant to be a rare occurrence (Id.)

With particular respect to a claim drawn to a genus, the written description requirement for a claimed genus may be satisfied through description of a representative number of species which have a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus (Written Description Guidelines at 1106). There may be situations where one species is a "representative number of species" (Id.). Satisfactory disclosure depends on whether one of ordinary skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed (Id.). In the present patent application, as filed, the claimed invention is described in sufficient detail to allow one of ordinary skill in the art to recognize that applicants had possession of the claimed invention having the distinguishing characteristics of (1) being of 5 to 20 or 20 to 40 amino acid residues in length, (2) capable of binding to SEQ. ID. NO: 174, (3) inhibiting ristocetin induced aggregation of platelets and (4) having a three dimensional structure complementary to the three dimensional structure of the second peptide. Each of the numerous species listed on page 17, line 23 to page 18, line 15 is described as having these distinguishing features. Accordingly, the rejection of claims 9 and 11 for lack of written description is improper and should be withdrawn.

The rejection of claims 9 and 11 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed in view of the above amendments.

The present application, as filed, adequately describes how to make and use the present invention. In particular, the specification describes a method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims without requiring undue experimentation. Experimentation is permissible, if routine or if the specification provides a reasonable amount of guidance (Manual of Patent Examining Procedure ("MPEP") 2164.05). Accordingly, one of ordinary skill in the art, based on the information contained in the specification describing identifying anti-mimotope peptides (page 17, lines 9-22; page 27, line 5 to page 32, line 23) and the skill of the art in methodology for identifying anti-mimotope peptides that bind to particular mimotope peptides (as disclosed in references cited in the specification and in the amendment dated February 8, 2002), could make and use the claimed invention. Accordingly, applicants contend that the identification of peptides that bind to the specifically enumerated mimotope sequence is enabled in view of the disclosure in the specification and the state of the art as of the filing date of the subject application. Furthermore, the claims, in addition to being limited in regard to the particular mimotope sequence, are also limited to those peptides that inhibit ristocetin induced aggregation of platelets. The identification of such peptides which have this desired functional property can be routinely done using, for example, the methodology disclosed in the specification at page 38, line 13 through page 40, line 20. Accordingly, the rejection of claims 9 and 11 for lack of enablement is improper and should be withdrawn.

The rejection of claim 11 under 35 USC § 112(second paragraph) for indefiniteness is respectfully traversed in view of the above amendments.

In view of the above amendments and remarks, applicants respectfully submit that the application is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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Date

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12/30/02
Date

Karla M. Weyand

U.S. Serial No. 09/258,947
Marked-Up Version of Claims

9. (Four Times Amended) An isolated peptide of [3] 5 to [about 100] 20 or 20 to 40 amino acids residues in length capable of binding to a second peptide having an amino acid sequence as shown in SEQ ID NO:174 [SEQ ID NOs: 1-21, 23-75, or 77-81], wherein the isolated peptide inhibits ristocetin induced aggregation of platelets, and wherein the isolated peptide has a three dimensional structure complementary to the three dimensional structure of the second peptide.

11. (Twice Amended) An isolated peptide of [3] 5 to [about 100] 20 or 20 to 40 amino acid residues in length which inhibits ristocetin induced aggregation of platelets, the isolated peptide being identified by:

selecting a library of test peptides, each test peptide being of [3] 5 to [about 100] 20 or 20 to 40 amino acid residues in length;

exposing the library of test peptides to a sample peptide consisting of an amino acid sequence as shown in SEQ ID NO:174 [SEQ ID NOs: 1-21, 23-75, or 77-81];

selecting test peptides from the library that binds to the sample peptide;

screening the selected test peptides for ability to inhibit ristocetin induced aggregation of platelets; and

identifying the screened test peptides that inhibit ristocetin induced aggregation of platelets to isolate the peptide of 5 to 20 or 20 to 40 amino acid residues in length which inhibits ristocetin induced aggregation of platelets.